



26 January 2017
EMA/PRAC/5725/2017
Pharmacovigilance Risk Assessment Committee (PRAC)

New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 9-12 January 2017 PRAC

The product information wording in this document is extracted from the document entitled 'PRAC recommendations on signals' which contains the whole text of the PRAC recommendations for product information update, as well as some general guidance on the handling of signals. It can be found [here](#) (in English only).

New text to be added to the product information is underlined. Current text to be deleted is ~~struck through~~.

1. Azacitidine – Pericarditis and pericardial effusion (EPITT no 18733)

Summary of product characteristics

4.8. Undesirable effects

Tabulated list of adverse reactions

System Organ Class	Very common	Common	Uncommon	Rare	Not known
Cardiac disorders		<u>Pericardial effusion</u>			

Package leaflet

4. Possible side effects

Common side effects (may affect up to 1 in 10 people)

- Collection of fluid around the heart (pericardial effusion)



2. Propofol; valproate – Pharmacokinetic drug interaction leading to an increased propofol exposure (EPITT no 18696)

Summary of product characteristics (propofol)

4.5. Interaction with other medicinal products and other forms of interaction

A need for lower propofol doses has been observed in patients taking valproate. When used concomitantly, a dose reduction of propofol may be considered.